

# Risk Assessment Guidance for Superfund:

Volume III - Part A, Process for Conducting Probabilistic Risk Assessment





EPA 540-R-02-002 OSWER 9285.7-45 PB2002 963302 www.epa.gov/superfund/RAGS3A/index.htm December 2001

Superfund

# Risk Assessment Guidance for Superfund: Volume III - Part A, Process for Conducting Probabilistic Risk Assessment

Office of Emergency and Remedial Response U.S. Environmental Protection Agency Washington, DC 20460



#### **DISCLAIMER**

This document provides guidance to EPA Regions concerning how the Agency intends to exercise its discretion in implementing one aspect of the CERCLA remedy selection process. The guidance is designed to implement national policy on these issues.

Some of the statutory provisions described in this document contain legally binding requirements. However, this document does not substitute for those provisions or regulations, nor is it a regulation itself. Thus, it cannot impose legally-binding requirements on EPA, States, or the regulated community, and may not apply to a particular situation based upon the circumstances. Any decisions regarding a particular remedy selection decision will be made based on the statute and regulations, and EPA decision makers retain the discretion to adopt approaches on a case-by-case basis that differ from this guidance where appropriate.

Interested parties are free to raise questions and objection about the substance of this guidance and the appropriateness of the application of this guidance to a particular situation, and the Agency welcomes public input on this document at any time. EPA may change this guidance in the future.

### ABOUT THE REVISION

WHATITIS

EPA's *Process for Conducting Probabilistic Risk Assessment* is an update of the 1989 *Risk Assessment Guidance for Superfund (RAGS)*. It is Volume III, an update to the existing two-volume set of RAGS. Volume III: Part A provides policy and guidance on conducting probabilistic risk assessment for both human and ecological receptors.

Who it's for

RAGS Volume III: Part A is written primarily for risk assessors. Risk assessment reviewers, remedial project managers, and risk managers involved in Superfund site cleanup activities will also benefit from this addition to RAGS.

WHAT'S NEW

RAGS Volume III: Part A provides guidance on applying probabilistic analysis to both human health and ecological risk assessment. New information and techniques are presented that reflect the views of EPA Superfund program. A tiered approach is described for determining the extent and scope of the modeling effort that is consistent with the risk assessment objectives, the data available, and the information that may be used to support remedial action decisions at Superfund hazardous waste sites.

RAGS Volume III: Part A contains the following information:

- For the risk assessor—updated policies and guidance; discussion and examples of Monte Carlo modeling techniques for estimating exposure and risk.
- For the risk manager and the remedial project manager—an introduction to PRA, a chapter on communicating methods and results of PRA with the public, and a chapter on the role of PRA in decision making.

# TABLE OF CONTENTS

	ents
Preface	i
1.0	What is the Purpose of RAGS Volume 3 Part A? ii
2.0	What is Probabilistic Risk Assessment and how is it used in Risk Characterization? ii
3.0	What are the Advantages and Disadvantages of PRA for Remedial Decisions? iii
4.0	How is RAGS Volume 3, Part A Organized? iii
5.0	What are the Key Guiding Concepts in RAGS Volume 3: Part A?iii
References fo	r Preface
Chapter 1	Overview of Probabilistic Approach to Risk Assessment
1.0	Introduction
1.1	The Role of Risk Assessment in Superfund1-4
	1.1.1 Risk Assessment in the United States
	1.1.2 Risk Assessment at EPA
	1.1.3 Risk Assessment in Superfund
	1.1.4 Probabilistic Risk Assessment and Its Role in Superfund 1-7
1.2	Basic Concepts of Probabilistic Risk Assessment
	1.2.1 What is PRA? 1-10
	1.2.2 What is a Monte Carlo Simulation?
	1.2.3 Why is Variability Important in Risk Assessment? How is it Addressed
	by the Point Estimate and Probabilistic Approaches? 1-15
	1.2.4 Why is Uncertainty Important in Risk Assessment? How is Uncertainty
	Addressed by the Point Estimate and Probabilistic Approaches? 1-17
	1.2.5 Reasonable Maximum Exposure at the High-end
1.3	Advantages and Disadvantages of Point Estimate and Probabilistic Approaches 1-21
1.4	Conducting an Acceptable PRA1-24
	1.4.1 Key Policies for Applying PRA at Superfund Sites
1.5	Organization of the Guidance
1.6	Next Steps for PRA Implementation
References fo	r Chapter 1
Exhibit 1-1	Definitions for Chapter 1
Exhibit 1-2	Nine Criteria for Evaluation of Cleanup Alternatives
Exhibit 1-3	Cancer and Noncancer Risk Models
Exhibit 1-4	Use a PDF and CDF To Display:
Exhibit 1-5	Quantifying Variability and Uncertainty1-20
Exhibit 1-6	Advantages and Disadvantages of Point Estimate Approach
Exhibit 1-7	Advantages and Disadvantages of Probabilistic Risk Assessment
Figure 1-1	Example of a normal distribution that characterizes variability in adult body weight 1-12
Figure 1-2	Conceptual model of Monte Carlo analysis
Figure 1-3	Example of a probability distribution for risk illustrating the 95th percentile and two
	different risk levels of concern (A and B)1-16

Figure 1-4	Illustration of "Vertical" and "Horizontal" Confidence Intervals (or limits) on a riestimate	
Chapter 2	Workplan and The Tiered Approach	2-1
2.0	Introduction	
2.1	Workplan	
2.2	Special Administrative Considerations in PRA	
	2.2.1 Scoping of PRA	
	2.2.1.1 PRA Scope of Work for Fund-lead Sites	
	2.2.1.2 PRP Scope of Work for PRP-Lead Sites	
	2.2.2 Development of Probability Distributions	
	2.2.3 EPA Review of PRA Documents	
	2.2.5 Response to Comments on PRA	
	2.2.6 Administrative Record	
	2.2.7 Communication with Stakeholders	
	2.2.8 Communication with EPA Management	
2.3	Overview of the Tiered Approach	
2.3	2.3.1 Getting Started	
	2.3.2 Tier 1	
	2.3.3 Tier 2	
	2.3.4 Tier 3	
	2.3.5 Flexibility in Defining Tiers	2-18
References for	or Chapter 2	2-19
Exhibit 2-1	Definitions for Chapter 2	2-2
Exhibit 2-2	Examples of Important Contents of A PRA Workplan	
Exhibit 2-3	Stakeholders Potentially Involved in EPA's Decision-Making Process for PRA	
Exhibit 2-4	Typical Elements of Tier 1 Risk Assessment	2-11
Exhibit 2-5	Typical Elements of Tier 2 Risk Assessment	
Exhibit 2-6	Typical Elements of Tier 3 Risk Assessment	2-17
Figure 2-1	Schematic Diagram of Tiered Approach	
Figure 2-2	Schematic diagram of deliberation/decision cycle in the tiered process for PRA	2-10
Chapter 3	Using Probabilistic Analysis in Human Health Assessment	3-1
3.0	Introduction	3-1
3.1	Characterizing Variability In Exposure Variables	
	3.1.1 Developing Distributions For Exposure Variables	
	3.1.2 Characterizing Risk Using PRA	
3.2	Role of the Sensitivity Analysis	
3.3	Exposure Point Concentration Term	
3.4	Characterizing Uncertainty in Exposure Variables	
	3.4.1 Parameter Uncertainty	
	3.4.2 Scenario and Model Uncertainty	
3.5	Example of PRA for Human Health	3-17

References for	or Chapter 3	3-27					
Exhibit 3-1	General Equation for Exposure	3-1					
Exhibit 3-2	Definitions for Chapter 3						
Exhibit 3-3	Equation for Cancer Risk						
Exhibit 3-4	Equation for Noncancer Hazard Quotient						
Exhibit 3-5	Using the Tiered Process for PRA Hypothetical Case Study for Human Health Risk						
	Assessment						
Exhibit 3-6	Risk Equations						
Figure 3-1	Example of a frequency distribution for adult drinking water ingestion rates	3-4					
Figure 3-2	Hypothetical PRA results showing a PDF and CDF						
Figure 3-3	CDFs of risk based on Monte Carlo simulations described in Table 3-2	3-16					
Figure 3-4	CDFs of risk based on Monte Carlo simulations described in Table 3-2	3-16					
Figure 3-5	Site map for future wildlife refuge	3-22					
Figure 3-6	Results of sensitivity analysis for preliminary 1-D MCA (Tier 2)	3-26					
Table 3-1	Methods for characterizing parameter uncertainty with Monte Carlo						
	simulations	3-12					
Table 3-2	Example of 1-D MCA and 2-D MCA	3-14					
Table 3-3	Concentrations in Surface Soil (mg/kg)	3-22					
Table 3-4	Exposure Parameters used in Point Estimate Analysis	3-24					
Table 3-5	Point Estimate Risks and Exposure Pathway Contributions						
Table 3-6	Input Distributions for Exposure Variables used in 1-D MCA for Variability						
Table 3-7	1-D MCA Risk Estimates using Preliminary Inputs						
Table 3-8	Exposure Duration Survey Results						
Table 3-9	Refined Point Estimate and 1-D MCA Risk Estimates						
Chapter 4	Probabilistic Analysis in Ecological Risk Assessment	4-1					
4.1	Introduction	4-1					
	4.1.1 Basic Approach for Performing Ecological Risk Assessments	4-1					
	4.1.2 Predictive vs Observational Approaches						
	4.1.3 Potential Advantages and Limitations of Probabilistic Methods in ERA.						
	4.1.4 Focus of This Chapter						
4.2	Deciding If and When to Use PRA in Ecological Risk Assessment						
	4.2.1 Technical Considerations						
	4.2.2 Cost and Schedule Considerations	4-11					
4.3	Problem Formulation	4-11					
4.4	Modeling Variability in Exposure						
	4.4.1 Characterizing Variability in Dose						
	4.4.2 Characterizing Variability in Exposure Concentration						
4.5	Modeling Variability in Toxicity						
	4.5.1 Variability in Response Among Members of a Population						
	4.5.2 Variability in Response Among Species						
4.6	Modeling Variability in Risk						
	4.6.1 Variability in Hazard Quotient						
	4.6.2 Variability in Response						
	4.6.3 Joint Probability Curves						
	,						

4.7	Modeling Uncertainty in Ecological Risk Assessments	4-31				
	4.7.1 Uncertainty in Exposure	4-31				
	4.7.2 Uncertainty in Toxicity					
	4.7.4 Uncertainty in Response	4-34				
	4.7.3 Uncertainty in Hazard Quotient					
4.8	Interpreting Results of an Ecological PRA					
4.9	Guidelines For Planning And Performing a Probabilistic ERA					
	4.9.1 Planning an Ecological PRA					
	4.9.2 Evaluating an Ecological PRA					
4.10	Example of the Tiered Process in ERA					
References for	r Chapter 4	4-49				
Exhibit 4-1	Definitions for Chapter 4	4-3				
Exhibit 4-2	Ecological Risk Assessment Guidance and Policy Directives	4-4				
Exhibit 4-3	Modeling Variability in Response for a Dichotomous Endpoint					
Exhibit 4-4	Modeling Variability in Response for a Continuous Endpoint	4-19				
Exhibit 4-5	Hypothetical Species Sensitivity Distribution					
Exhibit 4-6	Modeling Variability in a Dichotomous Response					
Exhibit 4-7	Modeling Variability in a Continuous Response					
Exhibit 4-8	Example Elements of a Workplan for Ecological PRA					
Exhibit 4-9	Checklist for Including a PRA as Part of the ERA					
Exhibit 4-10	Refined Screening Point Estimate Inputs and Results					
Exhibit 4-11	Screening Level PRA Calculations of HQ Distribution	4-45				
Exhibit 4-12	· · · · · · · · · · · · · · · · · · ·					
Figure 4-1	Ecological Risk Assessment Framework (U.S. EPA, 1992a)					
Figure 4-2	Eight-step Ecological Risk Assessment Process for Superfund	4-5				
Figure 4-3	Example of cases where use of PRA may be helpful	4-10				
Figure 4-4	Example Graphical Presentations of Dose Distributions	4-14				
Figure 4-5	Example Comparison of Exposure Distribution to TRV	4-22				
Figure 4-6	Example Distribution of HQ Values	4-23				
Figure 4-7	Example Presentation of Species Sensitivity Distribution	4-25				
Figure 4-8	Example Joint Probability Curve.	4-30				
Figure 4-9	Example Presentation of Uncertainty in Exposure	4-31				
Figure 4-10	Example Presentation of Uncertainty in Response	4-35				
Figure 4-11	Example Presentation of Uncertainty in Exposure and TRV	4-36				
Figure 4-12	Example Presentation of Uncertainty in HQ Estimates					
Chapter 5	Probabilistic Risk Assessment and Preliminary Remediation Goals	5-1				
5.0	Introduction					
5.1	General Concepts Regarding EPCs and PRGs					
	5.1.1 Sources of Uncertainty in the EPC					
	<ul><li>5.1.2 Pre- and Post-Remediation Exposure Point Concentrations</li><li>5.1.3 Remediation Action Levels and 95% UCL Calculation</li></ul>	5-6				
	Methods	5-7				
	5.1.4 Consideration of Risk from Acute Toxicity					

5.1.5 Characterization of Uncertainty in the EPC: Point Estimates	
and Distributions	5-8
5.1.6 Multiple Chemicals	5-9
When to Use PRA for Developing PRGs	5-9
Methods for Developing PRGs	
* *	
Chapter 5	5-24
T	
Summaries of Some Key Terms	5-1
•	
•	
$\mathcal{G}$	
A hypothetical example of the use of iterative methods	5-12
<b>31</b>	
Soil sample	5-16
	5-17
<u> </u>	5-23
Communicating Risks and Uncertainties in Probabilistic Risk Assessments	6-1
Introduction	6-1
Stakeholder Involvement	6-4
Communication and Presentation	6-5
6.2.1 Communication of PRA With Concerned Citizens, Other Stakeholders, and	
	6-6
*	
1	
Č	
Perception of Risk And Uncertainty	
	S.1.6 Multiple Chemicals When to Use PRA for Developing PRGs Methods for Developing PRGs Backcalculation  5.4.1 Difficulties with Backcalculation Iterative Methods 5.5.1 Iterative Reduction 5.5.2 Iterative Truncation 5.5.3 Example of Iterative Methods 5.5.4 Multiple Exposure units and Iterative Methods PRGs for Groundwater PRGs for Other Contaminated Media Measurement of Attainment Summary of Recommended Methods Chapter 5  Summaries of Some Key Terms Definitions for Chapter 5 Criteria for Iterative Truncation Example of Iterative Methods Evaluation of Alternative RALs Using Iterative Truncation A hypothetical example of the use of iterative methods Lognormal probability plot of soil concentrations, including 4 nondetects Hypothetical example of a mixed, bimodal distribution.  Soil sample Pre- and Post-Remediation EPCs (95% UCLs) for Chemical X in Surface Soil Samples Summary of Potential Methods for PRG Development by Environmental Medium  Communicating Risks and Uncertainties in Probabilistic Risk Assessments  Introduction Stakeholder Involvement Communication of PRA With Concerned Citizens, Other Stakeholders, and Managers: An Overview 6.2.2 Steps for Communication of the Results of the PRA Communicating Differences Between Point Estimate and PRA Graphical Presentation of PRA Results to Various Audiences 6.4.1 Public Meeting 6.4.2 EPA Senior Staff 6.4.3 Press Releases

6.6	Trust and Credibility	. 6-21				
6.7	Communication Issues for RPMs	. 6-21				
References fo	or Chapter 6	. 6-23				
	References					
Exhibit 6-1	Definitions for Chapter 6					
Exhibit 6-2						
Exhibit 6-3						
Exhibit 6-4	Key Considerations in Developing Understandable Material	6-8				
Figure 6-1	Hypothetical PRA results showing a PDF and CDF	. 6-12				
Figure 6-2	Results of a sensitivity analysis shown as a pie chart and tornado plot	. 6-16				
Figure 6-3	The results of a 2-D MCA	. 6-17				
Table 6-1	Examples of Graphics for Communicating PRA Concepts in this					
	Guidance Document	. 6-14				
Chapter 7	Role of the PRA in Decision Making	7-1				
7.0	Introduction	7-1				
7.1	General Principles of Risk-Based Decision Making In Superfund					
7.2	Interpreting A Risk Distribution					
	7.2.1 What Is A Distribution Of Risk And What Does It Look Like?					
	7.2.2 What Is the RME Range?					
	7.2.3 Relating the Risk Distribution to the Risk Management Goal for					
	Human Health	7-4				
	7.2.4 Relating the Risk Distribution to the Risk Management Goal for					
	Ecological Risk Assessment	7-6				
7.3	Factors to Consider in Choosing the Percentile for the RME					
7.4	Uncertainty Associated with the Use of the 99.9th Percentile					
7.5	Moving From A PRG To A Remedial Goal					
References fo	or Chapter 7	. 7-15				
D 1212 5 1		7.0				
Exhibit 7-1	Definitions for Chapter 7	7-2				
Exhibit 7-2	Examples of Demographic, Cultural, and Behavioral Factors that Can	7 7				
Erchibit 7.2	Affect Exposure					
Exhibit 7-3	Examples of Physical or Geographical Factors that Can Affect Exposure					
Exhibit 7-4	Examples of Toxicity Considerations	/-9				
Figure 7-1	Hypothetical PRA results showing a CDF for lifetime excess cancer risk					
Figure 7-2	Example of a probability distribution for risk illustrating the 95 <sup>th</sup> percentile					
Figure 7-3	Box and whisker plots characterizing uncertainty in the RME	. 7-10				
Figure 7-4	Example of graphic showing variability in risk (i.e., RME range, or 90th to 99.9th					
	percentiles) associated with different choices of PRG for plutonium in soil (pCi/g).	7-14				
Figure 7-5	Example of graphic showing uncertainty in a 95 <sup>th</sup> percentile of the risk distribution					
	associated with the same choices of PRG as Figure $7.4$	7_14				

Appen	dix A	Sensitivity Analysis: How Do We Know What's Important?	4-1
A.0	Introdu	action	<b>A-</b> 1
	A.1.0	Utility of Sensitivity Analysis	A-3
	A.2.0	Common Methods of Sensitivity Analysis	-10
	A.2.1	Tier 1 Approaches	-11
		A.2.1.1 Percentage Contribution of Exposure Pathways to Total Risk A	-12
		A.2.1.2 Inspection of Risk Equation	-13
		A.2.1.3 Sensitivity Ratio (SR)	-13
		A.2.1.4 Sensitivity Score	
	A.2.2	Tier 2 Approaches	
		A.2.2.1 Graphical Techniques	-21
		A.2.2.2 Correlation Coefficients	
		A.2.2.3 Focusing on the RME Range of the Risk Distribution	
		A.2.2.4 Inspection	
	A.3.0	Advanced Concepts in Sensitivity Analysis A	
	A.3.1	Relating the Change in Risk to the Change in Input Variable X	
	A.3.2	Normalized Partial Derivative	
	A.3.3	Regression Analysis: R <sup>2</sup> , Pearson r, and Partial Correlation Coefficients	
	11.0.0	A.3.3.1 Calculations of $R^2$ and Adjusted $R^2$	
		A.3.3.2 Relative Partial Sum of Squares (RPSS)	
		A.3.3.3 Spearman's Rank Correlation Coefficient (Rho)	
Referei	nces for	Appendix A	-37
Exhibit	A-1	Definitions for Appendix A	
Exhibit	A-2	Utility of Sensitivity Analysis	A-3
Exhibit	A-3	Some Key Indices of Sensitivity Analysis A	-10
Exhibit	A-4	Categories of Solutions for Sensitivity Ratios of	
		Multipicative or Additive Equations	-17
Exhibit	A-5	Simplifying Assumptions in Regression Analysis	-32
Figure	A-1	Results of 2-D MCA in which parameters of input distributions describing variability	
г.	4 2	assumed to be random values.	<b>A-</b> 9
Figure	A-2	Scatterplots of simulated random values from a 1-D MCA of variability. The output	
		from the model is a contaminant concentration in soil (C) that corresponds with a	22
		prescribed (fixed) level of risk for a hypothetical population	
Figure	A-3	Scatterplots of simulated random values from a 1-D MCA of variability for example in	
		Section A.2.0	-24
Figure	A-4	Top panel - bar graph showing the $r^2$ values (square of Spearman rank correlation	
		coefficient), a metric for the dependence of HI on exposure factors based on 1-D MCA	1
		for variability. Bottom panel - bar graph, sometimes referred to as "tornado plot",	
		showing rank correlation coefficient	
Figure		Hypothetical 2-D response surface for $Y$ given one input variable: $Y=F(X)$	-29
Figure	A-5b	Hypothetical 3-D response surface for <i>Y</i> given two input	
		variables: $Y = f(X_1, X_2)$	-30
Figure	A-5c	Hypothetical 3-D response surface when <i>Y</i> is a linear function of two input variables:	
		$Y=f(X_1, X_2)$	-30

	A-1	Overview of Sensitivity Analysis Methods Applicable in	A 1
Table .	۸ 2	Tiers 1, 2, and 3 of a PRA	
Table A-2		example of HI associated with occupational exposure via water and soil ingestion.	
Table A-3		Percent contribution of exposure pathways to HI for the example	71-11
		in Section A.2	A-12
Table .	A-4	Results of the Sensitivity Ratio (SR) approach applied to the hypothetical example	
		RME HI given in Section A.2.0. Includes <i>both</i> soil ingestion and tap water ingesti	
		pathways	
Table .	A-5	Results of the Sensitivity Ratio (SR) approach applied to the hypothetical example	
		RME HI given in Section A.2.0. Includes <i>only</i> tap water	
		ingestion pathway	. A-15
Table .	A-6	Examples of algebraic solutions to Sensitivity Ratio calculations for additive and	
		multiplicative forms of risk equations	. A-17
Table .	A-7	Calculation of coefficient of variation (CV = SD / Mean) for the hypothetical	
		example of RME HI given in Section A.2.0	. A-19
Table .	A-8	Results of the Sensitivity Score (Score) approach applied to the hypothetical	
		example of RME HI given in Section A.2.0	. A-20
Table .	A-9	Results of Tier 2 sensitivity analyses applied to hypothetical example in	
		Section A.2.0: Pearson product moment correlations and Spearman	
		rank correlations	. A-22
Annon	dir D	Coloction and Fitting of Distributions	D 1
Appen	iaix B	Selection and Fitting of Distributions	Б-1
B.0	Introdu	action	B-1
	B.1.0	Conceptual Approach for Incorporating a Probability Distribution in a PRA	
	B.1.0 B.2.0		В-3
		Conceptual Approach for Incorporating a Probability Distribution in a PRA	B-3
	B.2.0	Conceptual Approach for Incorporating a Probability Distribution in a PRA  Preliminary Sensitivity Analysis	B-3 B-4 B-5
	B.2.0 B.3.0	Conceptual Approach for Incorporating a Probability Distribution in a PRA  Preliminary Sensitivity Analysis	B-3 B-4 B-5
	B.2.0 B.3.0 B.3.1	Conceptual Approach for Incorporating a Probability Distribution in a PRA  Preliminary Sensitivity Analysis	B-3 B-4 B-5 B-6
	B.2.0 B.3.0 B.3.1 B.3.2	Conceptual Approach for Incorporating a Probability Distribution in a PRA Preliminary Sensitivity Analysis	B-3 B-4 B-5 B-6 B-12 . B-13
	B.2.0 B.3.0 B.3.1 B.3.2 B.4.0	Conceptual Approach for Incorporating a Probability Distribution in a PRA Preliminary Sensitivity Analysis What Does The Distribution Represent? Concepts of Population and Sampling Considering Variability and Uncertainty in Selecting and Fitting Distributions Do Data Exist To Select Distributions?	B-3 B-4 B-5 B-6 B-12 B-13
	B.2.0 B.3.0 B.3.1 B.3.2 B.4.0 B.4.1	Conceptual Approach for Incorporating a Probability Distribution in a PRA Preliminary Sensitivity Analysis What Does The Distribution Represent? Concepts of Population and Sampling Considering Variability and Uncertainty in Selecting and Fitting Distributions Do Data Exist To Select Distributions? What are Representative Data? The Role of Expert Judgment Fitting Distributions to Data	B-3 B-4 B-5 B-6 B-12 B-13 B-14 B-15
	B.2.0 B.3.0 B.3.1 B.3.2 B.4.0 B.4.1 B.4.2	Conceptual Approach for Incorporating a Probability Distribution in a PRA Preliminary Sensitivity Analysis What Does The Distribution Represent? Concepts of Population and Sampling Considering Variability and Uncertainty in Selecting and Fitting Distributions Do Data Exist To Select Distributions? What are Representative Data? The Role of Expert Judgment	B-3 B-4 B-5 B-6 B-12 B-13 B-14 B-15
	B.2.0 B.3.0 B.3.1 B.3.2 B.4.0 B.4.1 B.4.2 B.5.0 B.5.1 B.5.2	Conceptual Approach for Incorporating a Probability Distribution in a PRA Preliminary Sensitivity Analysis What Does The Distribution Represent? Concepts of Population and Sampling Considering Variability and Uncertainty in Selecting and Fitting Distributions Do Data Exist To Select Distributions? What are Representative Data? The Role of Expert Judgment Fitting Distributions to Data Considering the Underlying Mechanism Empirical Distribution Functions (EDFs)	B-3 B-4 B-5 B-6 . B-12 . B-14 . B-15 . B-16
	B.2.0 B.3.0 B.3.1 B.3.2 B.4.0 B.4.1 B.4.2 B.5.0 B.5.1	Conceptual Approach for Incorporating a Probability Distribution in a PRA Preliminary Sensitivity Analysis What Does The Distribution Represent? Concepts of Population and Sampling Considering Variability and Uncertainty in Selecting and Fitting Distributions Do Data Exist To Select Distributions? What are Representative Data? The Role of Expert Judgment Fitting Distributions to Data Considering the Underlying Mechanism Empirical Distribution Functions (EDFs) Graphical Methods for Selecting Probability Distributions	B-3 B-4 B-5 B-6 B-12 B-14 B-15 B-16 B-17 B-16 B-17
	B.2.0 B.3.0 B.3.1 B.3.2 B.4.0 B.4.1 B.4.2 B.5.0 B.5.1 B.5.2 B.5.3 B.5.4	Conceptual Approach for Incorporating a Probability Distribution in a PRA Preliminary Sensitivity Analysis What Does The Distribution Represent? Concepts of Population and Sampling Considering Variability and Uncertainty in Selecting and Fitting Distributions Do Data Exist To Select Distributions? What are Representative Data? The Role of Expert Judgment Fitting Distributions to Data Considering the Underlying Mechanism Empirical Distribution Functions (EDFs) Graphical Methods for Selecting Probability Distributions Parameter Estimation Methods	B-3 B-4 B-5 B-6 B-12 B-13 B-14 B-15 B-16 B-17 B-22 B-24
	B.2.0 B.3.0 B.3.1 B.3.2 B.4.0 B.4.1 B.4.2 B.5.0 B.5.1 B.5.2 B.5.3 B.5.4 B.5.5	Conceptual Approach for Incorporating a Probability Distribution in a PRA Preliminary Sensitivity Analysis What Does The Distribution Represent? Concepts of Population and Sampling Considering Variability and Uncertainty in Selecting and Fitting Distributions Do Data Exist To Select Distributions? What are Representative Data? The Role of Expert Judgment Fitting Distributions to Data Considering the Underlying Mechanism Empirical Distribution Functions (EDFs) Graphical Methods for Selecting Probability Distributions Parameter Estimation Methods Dealing with Correlations among Variables or Parameters	B-3 B-4 B-5 B-6 B-12 B-13 B-14 B-15 B-16 B-17 B-22 B-22 B-24
	B.2.0 B.3.0 B.3.1 B.3.2 B.4.0 B.4.1 B.4.2 B.5.0 B.5.1 B.5.2 B.5.3 B.5.4 B.5.5 B.5.6	Conceptual Approach for Incorporating a Probability Distribution in a PRA Preliminary Sensitivity Analysis What Does The Distribution Represent? Concepts of Population and Sampling Considering Variability and Uncertainty in Selecting and Fitting Distributions Do Data Exist To Select Distributions? What are Representative Data? The Role of Expert Judgment Fitting Distributions to Data Considering the Underlying Mechanism Empirical Distribution Functions (EDFs) Graphical Methods for Selecting Probability Distributions Parameter Estimation Methods Dealing with Correlations among Variables or Parameters Censored Data	B-3 B-4 B-5 B-6 B-12 B-13 B-14 B-15 B-16 B-17 B-22 B-24 B-26 B-28
	B.2.0 B.3.0 B.3.1 B.3.2 B.4.0 B.4.1 B.4.2 B.5.0 B.5.1 B.5.2 B.5.3 B.5.4 B.5.5 B.5.6 B.5.7	Conceptual Approach for Incorporating a Probability Distribution in a PRA Preliminary Sensitivity Analysis What Does The Distribution Represent? Concepts of Population and Sampling Considering Variability and Uncertainty in Selecting and Fitting Distributions Do Data Exist To Select Distributions? What are Representative Data? The Role of Expert Judgment Fitting Distributions to Data Considering the Underlying Mechanism Empirical Distribution Functions (EDFs) Graphical Methods for Selecting Probability Distributions Parameter Estimation Methods Dealing with Correlations among Variables or Parameters Censored Data Truncation	B-3 B-4 B-5 B-6 B-12 B-15 B-15 B-16 B-12 B-22 B-22 B-24 B-28 B-30
	B.2.0 B.3.0 B.3.1 B.3.2 B.4.0 B.4.1 B.4.2 B.5.0 B.5.1 B.5.2 B.5.3 B.5.4 B.5.5 B.5.6 B.5.7	Conceptual Approach for Incorporating a Probability Distribution in a PRA Preliminary Sensitivity Analysis What Does The Distribution Represent? Concepts of Population and Sampling Considering Variability and Uncertainty in Selecting and Fitting Distributions Do Data Exist To Select Distributions? What are Representative Data? The Role of Expert Judgment Fitting Distributions to Data Considering the Underlying Mechanism Empirical Distribution Functions (EDFs) Graphical Methods for Selecting Probability Distributions Parameter Estimation Methods Dealing with Correlations among Variables or Parameters Censored Data Truncation Assessing Quality of the Fit	B-3 B-4 B-5 B-6 B-12 B-13 B-14 B-15 B-16 B-17 B-22 B-22 B-24 B-28 B-30 B-31
	B.2.0 B.3.0 B.3.1 B.3.2 B.4.0 B.4.1 B.4.2 B.5.0 B.5.1 B.5.2 B.5.3 B.5.4 B.5.5 B.5.6 B.5.7 B.6.0 B.6.1	Conceptual Approach for Incorporating a Probability Distribution in a PRA Preliminary Sensitivity Analysis What Does The Distribution Represent? Concepts of Population and Sampling Considering Variability and Uncertainty in Selecting and Fitting Distributions Do Data Exist To Select Distributions? What are Representative Data? The Role of Expert Judgment Fitting Distributions to Data Considering the Underlying Mechanism Empirical Distribution Functions (EDFs) Graphical Methods for Selecting Probability Distributions Parameter Estimation Methods Dealing with Correlations among Variables or Parameters Censored Data Truncation Assessing Quality of the Fit What is a Goodness-of-Fit Test?	B-3 B-4 B-5 B-6 B-12 B-13 B-14 B-15 B-16 B-17 B-22 B-22 B-24 B-30 B-31 B-31
	B.2.0 B.3.0 B.3.1 B.3.2 B.4.0 B.4.1 B.4.2 B.5.0 B.5.1 B.5.2 B.5.3 B.5.4 B.5.5 B.5.6 B.5.7 B.6.0 B.6.1 B.6.2	Conceptual Approach for Incorporating a Probability Distribution in a PRA Preliminary Sensitivity Analysis What Does The Distribution Represent? Concepts of Population and Sampling Considering Variability and Uncertainty in Selecting and Fitting Distributions Do Data Exist To Select Distributions? What are Representative Data? The Role of Expert Judgment Fitting Distributions to Data Considering the Underlying Mechanism Empirical Distribution Functions (EDFs) Graphical Methods for Selecting Probability Distributions Parameter Estimation Methods Dealing with Correlations among Variables or Parameters Censored Data Truncation Assessing Quality of the Fit What is a Goodness-of-Fit Test? What are some common Goodness-of-Fit Techniques?	B-3 B-4 B-5 B-6 B-12 B-13 B-14 B-15 B-16 B-16 B-22 B-24 B-26 B-30 B-31 B-31
	B.2.0 B.3.0 B.3.1 B.3.2 B.4.0 B.4.1 B.4.2 B.5.0 B.5.1 B.5.2 B.5.3 B.5.4 B.5.5 B.5.6 B.5.7 B.6.0 B.6.1 B.6.2 B.6.3	Conceptual Approach for Incorporating a Probability Distribution in a PRA Preliminary Sensitivity Analysis What Does The Distribution Represent? Concepts of Population and Sampling Considering Variability and Uncertainty in Selecting and Fitting Distributions Do Data Exist To Select Distributions? What are Representative Data? The Role of Expert Judgment Fitting Distributions to Data Considering the Underlying Mechanism Empirical Distribution Functions (EDFs) Graphical Methods for Selecting Probability Distributions Parameter Estimation Methods Dealing with Correlations among Variables or Parameters Censored Data Truncation Assessing Quality of the Fit What is a Goodness-of-Fit Test? What are some common Goodness-of-Fit Techniques? Cautions Regarding Goodness-of-Fit Tests	B-3 B-4 B-5 B-12 B-13 B-14 B-15 B-16 B-17 B-22 B-24 B-26 B-30 B-31 B-31 B-33
	B.2.0 B.3.0 B.3.1 B.3.2 B.4.0 B.4.1 B.4.2 B.5.0 B.5.1 B.5.2 B.5.3 B.5.4 B.5.5 B.5.6 B.5.7 B.6.0 B.6.1 B.6.2 B.6.3 B.6.4	Conceptual Approach for Incorporating a Probability Distribution in a PRA Preliminary Sensitivity Analysis What Does The Distribution Represent? Concepts of Population and Sampling Considering Variability and Uncertainty in Selecting and Fitting Distributions Do Data Exist To Select Distributions? What are Representative Data? The Role of Expert Judgment Fitting Distributions to Data Considering the Underlying Mechanism Empirical Distribution Functions (EDFs) Graphical Methods for Selecting Probability Distributions Parameter Estimation Methods Dealing with Correlations among Variables or Parameters Censored Data Truncation Assessing Quality of the Fit What is a Goodness-of-Fit Test? What are some common Goodness-of-Fit Techniques? Cautions Regarding Goodness-of-Fit Tests Accuracy of the Tails of the Distribution	B-3 B-4 B-15 B-16 B-17 B-22 B-22 B-24 B-30 B-31 B-31 B-34 B-34
	B.2.0 B.3.0 B.3.1 B.3.2 B.4.0 B.4.1 B.4.2 B.5.0 B.5.1 B.5.2 B.5.3 B.5.4 B.5.5 B.5.6 B.5.7 B.6.0 B.6.1 B.6.2 B.6.3	Conceptual Approach for Incorporating a Probability Distribution in a PRA Preliminary Sensitivity Analysis What Does The Distribution Represent? Concepts of Population and Sampling Considering Variability and Uncertainty in Selecting and Fitting Distributions Do Data Exist To Select Distributions? What are Representative Data? The Role of Expert Judgment Fitting Distributions to Data Considering the Underlying Mechanism Empirical Distribution Functions (EDFs) Graphical Methods for Selecting Probability Distributions Parameter Estimation Methods Dealing with Correlations among Variables or Parameters Censored Data Truncation Assessing Quality of the Fit What is a Goodness-of-Fit Test? What are some common Goodness-of-Fit Techniques? Cautions Regarding Goodness-of-Fit Tests	B-3 B-4 B-15 B-16 B-17 B-22 B-22 B-24 B-30 B-31 B-31 B-34 B-34

Exhibit B-1	Definitions for Appendix B	B-2
Exhibit B-2	General Strategy for Selecting and Fitting Distributions	B-3
Exhibit B-3	Factors to Consider in Selecting a Probability Distribution	B-16
Exhibit B-4	Variations of the EDF	B-22
Exhibit B-5	Estimating the area of a hypothetical exposure unit	B-24
Exhibit B-6	Criteria for Evaluating Parameter Estimation Methods	B-25
Exhibit B-7	Parameter Estimation Methods	
Exhibit B-8	Correlation of Input Variables for 1-D MCA of Variability	B-27
Exhibit B-9	Steps for Simulating Uncertainty in Linear Regression Equation Using a Bivariate Normal Distribution to Correlate Parameters $(\beta_0, \beta_1)$	B-47
Figure B-1	(page 1 of 2). Conceptual approach for incorporating probability distributions for variability in PRA	B-7
Figure B-1	(page 2 of 2). Conceptual approach for incorporating probability distributions for variability in PRA	B-8
Figure B-2a	(page 1 of 3). Conceptual approach for quantifying model and parameter uncertainty in PRA	B-9
Figure B-2a	(page 2 of 3). Conceptual approach for quantifying model and parameter	B-10
Figure B-2a	(page 3 of 3). Conceptual approach for quantifying model and parameter	B-11
Figure B-3	Comparison of step-wise EDF and linearized EDF for ingestion rate	B-38
Figure B-4	Graphical assessment of beta and lognormal distributions fit to the cumulative distribution reported in the literature (circles)	B-39
Figure B-5	Histograms of lead concentrations in quail breast muscle	B-41
Figure B-6	Lognormal probability plots of lead in mourning dove breast tissue	B-43
Figure B-7	Histograms of meal size	B-44
Figure B-8	Probability plot of meal size data	B-45
Figure B-9	Simple linear regression of zinc concentrations in soil and dust	
Figure B-10	Results of Monte Carlo simulation	B-49
Table B-1	Examples of Preliminary Distributions Based on Information Available	
Table B-2	Examples of Selected Probability Distributions for PRA	
Table B-3	Theoretical bounds and parameter values for selected distributions	
Table B-4	Strategies for conducting PRA based on available information	
Table B-5	Selected statistics for reported and fitted distributions for ingestion rate (mg/day).	
Table B-6	Sample values of lead concentration (ppm) in quail breast muscle	
Table B-7	Parameter estimates for lognormal distribution of lead concentrations (ppm)	
Table B-8	Meal size (g/meal)	B-44
Table B-9	Zinc concentrations in paired (i.e., co-located) soil and dust samples (ppm) for n=21 locations	B-48
Appendix C	Characterizing Variability and Uncertainty in the Concentration Term	<b>C</b> -1
C.0 The C	Concentration Term and the Exposure Unit	C-1
C.1.0	Variability in PRA	
C.1.1	Temporal Variability	C-2
C.1.2	Spatial Variability	
C.1.3	Example of Temporal and Spatial Variability	
C.1.4	Spatial and Temporal Variability for Different Exposure Media	

		C.1.4.2 Variability of Concentrations in Groundwater	. C-5
		C.1.4.3 Variability of Concentrations in Surface Water	. C-5
		C.1.4.4 Variability of Concentrations in Sediment	. C-5
		C.1.4.5 Variability of Concentrations in Fish	. C-5
		C.1.4.6 Examples of Temporal and Spatial Variability in the Concentration Term	
		for Selected Exposure Media	. С- <i>е</i>
	C.2.0	Nonrandom Exposures	
	C.3.0	Sources of Uncertainty in the Concentration Term	
	C.3.1	Quantification of Uncertainty Based on the Size of the Exposure Unit	
	0.0.1	C.3.1.1 When the Exposure Unit Is Smaller than the Site	
		C.3.1.2 When the Exposure Unit is the Same Size as the Site	
		C.3.1.3 When the Exposure Unit is Larger than the Site	
	C.4.0	Summary of Recommendations for the Concentration Term	
	C.5.0	Methods for Estimating Uncertainty in the Mean Concentration	
	C.5.1	Quantifying Uncertainty without Information About Locations of	0 10
	0.5.1	Samples and Receptors	C-12
	C.5.2	Quantifying Uncertainty with Information About Locations of	C-12
	0.3.2	Samples and Receptors	C-13
		Samples and receptors	C-12
Refer	ences for	Appendix C	C-14
ICICI	clices for	Appendix C	C-1-
Figur	e C-1	Spatial and temporal variability in contaminant concentrations in groundwater	C-7
rigui	C C-1	Spatial and temporal variability in containmant concentrations in groundwater	. C-
Table	C 1	Examples of temporal and spatial variability in selected media for the	
Table	; C-1	* * *	C = C
Takla	$C_{2}$	concentration term in common exposure scenarios	
Table	: C-2	Summary of factors that may be considered in developing an EPC	C-10
Anno	ndix D	Advanced Modeling Approaches for Characterizing Variability and Uncertain	ένD 1
Appe	iluix D	Advanced Moderning Approaches for Characterizing variability and Oncertain	tyD-1
D.0	Introdu	uction	D <sub>-</sub> 1
D.0	D.1.0	Expressing Variability and Uncertainty Simultaneously	
	D.1.0 D.2.0	Two-Dimensional Monte Carlo Analysis (2-D MCA)	
	D.2.0 D.3.0	Microexposure Event Analysis	
		*	
	D.4.0	Geospatial Statistics	
	D.4.1	*	
	D.4.2	Effective Sample Size (n*) and Degrees of Freedom	
	D.4.3	Assessment of Additional Site Sampling	
	D.4.4	Map Generalization	
	D.4.5	Implementation Issues Related to Georeferenced Data	
	D.5.0	Expert Judgment and Bayesian Analysis	D-16
Refer	ences for	Appendix D	D-25
	oit D-1	Definitions for Appendix D	
	oit D-2	Positive Spatial Autocorrelation	
	oit D-3	Examples of Risk Assessment Issues Linked to Geospatial Statistics	
Exhit	oit D-4	Effect of Spatial Autocorrelation (r) on Effective Sample Size $(n^*)$	
Enhil	oit D-5	Components of Bayes Theorem in PRA	$D_{-}1'$

Figure	D-1	Panel A shows a family of 20 CDFs for a hypothetical random variable. Panel B shows the "90% credible interval" for the CDF based on 2500 <i>simulations</i>
Figure	D-2	Diagram showing of a 2-D Monte Carlo model
Figure		Output from a 2-D MCA showing the estimated mean Hazard Quotient (HQ) and the
riguic	DJ	90% confidence interval D-5
Figure	D-4	Time Step for MEE
Figure		Flowchart showing general approach for Microexposure Event (MEE) analysis D-8
Figure		Hypothetical example showing the effect of model time step on the probability
8		distribution for soil and dust ingestion rate in children over a 1-year period D-9
Figure	D-7	Effect of an outlier on measured correlation
Figure	D-8	Conceptual model of Bayesian Monte Carlo analysis D-18
Figure	D-9	Expected Loss associated with various types of information incorporated into a generic
		uncertainty analysis
Figure	D-10	Conceptual model for evaluating the expected value of including uncertainty in a
		Bayesian Monte Carlo analysis
Appen	dix E	Definitions of Terms Relevant to PRA and References for Further Reading E-1
E.0	Definit	ions of Terms
	E.1	Additional Information E-14
Refere	nces for	Appendix E
Refere	nces for	Further Reading
Appen	dix F	Workplan and Checklist for PRA F-1
F.0	Introdu	nction
	F.1.0	Workplan
	F.2.0	Focal Points for PRA ReviewF-2
	F.3.0	Checklist for Reviewers
	F.4.0	Internal and External Review F-3
Refere	nces for	Appendix F
Exhibi	t F-1	Examples of Elements of the Workplan for PRA
Exhibi	t F-2	Key Focal Points for PRA Review
Table l	F-1	Example of a Generic Checklist for Reviewers
Appen	dix G	Frequently Asked Questions for PRA G-1
Refere	nces for	Appendix G
Appen	dix H	Index H-1

#### ACRONYMS AND ABBREVIATIONS

1-D MCA2-D MCAOne-dimensional Monte Carlo analysisTwo-dimensional Monte Carlo analysis

95% UCL 95% upper confidence limit

AM Arithmetic mean

ARARs Applicable or relevant and appropriate requirements

AT Averaging time

AWQC Ambient water quality criterion
BCa Bias correction acceleration method

BMD Benchmark dose

BMDS Benchmark dose software BMR Benchmark Response

BTAG Biological Technical Assistance Group

BW Body weight C Concentration

CAG Community advisory group
CDF Cumulative distribution function

CI Confidence interval

CIC Community involvement coordinator

CIP Community involvement plan

CLT Central limit theorem COC Chemical of concern

CQR Continuous quadratic regression

CSF Cancer slope factor
CTE Central tendency exposure
CV Coefficient of variation

DI Daily intake

DQO Data quality objectives

EC<sub>0</sub> Exposure concentration that produces zero effect

EC<sub>20</sub> Concentration that causes a 20% effect ECDF Empirical cumulative distribution function

ED Exposure duration

ED<sub>10</sub> Dose that causes a 10% effect EDF Empirical distribution function

EF Exposure frequency

EPA U.S. Environmental Protection Agency

EPC Exposure point concentration
ERA Ecological risk assessment
ERAF Risk Assessment Forum

ERAGS Ecological Risk Assessment Guidance for Superfund

EU Exposure unit

EVIU Expected value of including uncertainty

EVOI Expected value of information

EVPI Expected value of perfect information EVSI Expected value of sample information GIS Geographical Information Systems

GM Geometric mean GoF Goodness-of-Fit

GSD Geometric standard deviation

HEAST Health effects assessment summary table
HHEM Human Health Evaluation Manual

HI Hazard Index
HQ Hazard Quotient
IR Iterative reduction

Irsd Soil and dust ingestion rate

IRIS Integrated Risk Information System
LADD Life-time average daily intake
LCL Lower confidence limit

LED<sub>10</sub> Lowest effect dose - lower confidence bound for dose that causes a 10% effect

LHS Latin hypercube sampling

LOAEL Lowest-observed-adverse-effect level

LOD Limit of detection

LOEC Lowest-observed-effect-concentration

MCA Monte Carlo analysis

MCL Maximum contaminant levels
MDC Maximum detected concentration
MEE Microexposure Event Analysis
MLE Maximum Likelihood Estimation
MoMM Method of Matching Moments

NCP National Oil and Hazardous Substances Pollution Contingency Plan

NOAEL No-observed-adverse-effect level NOEC No-observed-effect-concentration

OLS Ordinary least squares

PBPK Physiologically-based pharmacokinetic

PCBs Polychlorinated biphenyls

pCi/g Picocuries/gram

PDF Probability density function

PDFu Probability distribution for variability PDFv Probability distribution for uncertainty

PMF Probability mass function

PPT Parts per trillion

PRA Probabilistic risk assessment
PRG Preliminary remediation goal
PRP Potentially responsible party
QAPP Quality Assurance Project Plan

RAGS Risk Assessment guidance for Superfund

RAL Remedial action level
RBC Risk based concentration

RCRA Resource Conservation and Recovery Act

RfC Reference concentration

RfD Reference dose RG Remediation goal

RI/FS Remedial Investigation/Feasibility Study

RME Reasonable maximum exposure

RMSE Root mean squared error ROD Record of decision ROS Rank order statistic

RPSS Relative partial sum of squares
RPM Remedial project manager
RSS Regression sum of squares

SCM Site conceptual model
SD Standard deviation
SE Standard error

SMDP Scientific/Management Decision Point

SOW Statement of Work SR Sensitivity ratio

SSD Species sensitivity distribution
SSE Sum of squares due to error
SSR Sum of squares due to regression

SST Sum of squares for total (regression plus error)
TAB Technical Assistance to Brownfields Community

TAG Technical assistance grant

TOSC Technical outreach services for communities

TRV Toxicity reference value
TSS Total sum of squares
UCL Upper confidence limit
VOI Value of information

## **AUTHORS, CONTRIBUTORS, AND REVIEWERS**

This manual was developed by EPA's Office of Emergency and Remedial Response. A number of individuals have reviewed and/or have been contributing authors of this document. Members of the EPA RAGS Volume III Workgroup, which was responsible for developing this document, included the following EPA headquarters and regional office staff.

#### RAGS VOLUME III WORKGROUP PARTICIPANTS

## **EPA HEADQUARTERS**

Office of Emergency and Remedial Response David A. Bennett

S. Steven Chang David E. Cooper Janine Dinan

Elizabeth Lee Hofmann

Office of Policy Economics and Innovation Timothy M. Barry

#### **EPA REGIONAL OFFICES**

Region 1	Ann-Marie Burke	Region 5	Amy Mucha James Chapman
Region 2	Audrey Galizia Marian Olsen	Region 6	Maria L. Martinez
Region 3	Nancy Rios Jafolla	Region 8	Susan Griffin Gerry Henningsen Dale Hoff
Region 4	Ted W. Simon Sharon R. Thoms	Region 10	Joe Goulet

Technical assistance and production support was provided to EPA in the development of this guidance under Contract Numbers GS-10F-0137K and GS-35F-0555K.

An earlier draft of this document was peer reviewed by a panel of experts at a peer-review workshop held in November 2000. In addition, individuals in EPA and from the public provided valuable comments on earlier drafts of this guidance during the peer review process.